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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

August 28, 2000

WARNING LETTER
CIN-WL-4099-0

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Shawn O. Lui
President
Lui's Bean Sprouts
4820 Oak Meadow Lane
Sylvania, Ohio 43650

Dear Mr. Lui:

An inspection of your sprout growing operation, located at 130 S. Superior Street, Toledo, Ohio, was conducted on August 3-7, 2000. During this inspection we found the conditions under which the sprouts are being grown are not sanitary because your facility has not adopted and implemented effective preventative controls. In particular, we found that your firm did not have a program to test the spent irrigation water for microbial contaminants such as Salmonella and Escherichia coli 0157:H7. This type of testing is necessary to help assure that the sprouts are safe and free from human pathogens.

The sprouts produced by your firm are considered to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because failure to test the irrigation water for microbial contaminants is considered to be an unsanitary condition that may render the sprouts injurious to the health of consumers.

A form FDA 483 List of Inspectional Observations was issued to you at the close of the inspection (copy enclosed). The FDA 483 listed deviations from the current Good Manufacturing Practices for human food (Title 21 Code of Federal Regulations Part 110) in addition to the failure to test spent irrigation water. Failure to correct these deviations promptly could result in regulatory action without further notice. The action could include seizure and/or injunction.

The listed deviations are not intended to be an all inclusive list of deficiencies at your facility. You are responsible for ensuring that your processing operations are in compliance with the Act and Good Manufacturing Practice (GMP) regulations.

During the inspection, you promised correction of each of the observations by September 7, 2000. Please notify this office in writing, within 15 working days of your receipt of this letter, of the specific steps you are taking to correct the deficiencies. If you cannot complete the corrections within 15 working days, state the reason for the delay and the time needed to complete the corrections. Your reply should be sent to Deborah Grelle, Director of Compliance, at the above address.

Sincerely,

Henry L. Fielden
Cincinnati District Director

Enc: FDA-483
HHS News FDA Issues Guidance to Enhance Safety of Sprouts October 25, 1999
Guidance for Industry Reducing Microbial Food Safety Hazards for Sprouted Seeds
Guidance for Industry Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production

Cc: Mike Okdie, President
Chariott Foods, Inc.
130 S. Superior Street
Toledo, OH 43602